

Inventor : Shalaby et al.
Serial No. : 09/890,013
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REMARKS

This reply is being filed concurrently with a Request for Continued Examination under 37 C.F.R. §1.114. Applicants respectfully request entry of the claim amendments submitted herewith.

Claims 43-58 are pending. Claims 44 and 48 are canceled without waiver or prejudice to their presentation in a later filed application claiming the benefit of priority of the present application. Claims 43, 45-47 and 49-58 are therefore pending in the application.

Claim 43 has been amended to explicitly claim the specific polyester discussed in the specification at page 30, line 17, referred to as "Rod Delivery System Type 3". No new matter has been introduced by this amendment.

Claims 43-58 stand rejected under 35 U.S.C. §103(e) as being unpatentable over PCT publication W097/39738 (hereinafter referred to as "Kinerton"). According to the Examiner, Kinerton teaches a polymer derived from ϵ -caprolactone and glycolic acids which may further contain tartaric acid units. Applicants respectfully contend that even though Kinerton disclosed polyesters made of monomers such as ϵ -caprolic acid and glycolic acid wherein free carboxylic acid groups can be incorporated into such a polyester by reaction with a polycarboxylic acid such as tartaric acid, there is no explicit teaching or suggestion in Kinerton to produce a polyester comprised of ϵ -caprolic acid, glycolic acid and tartaric acid monomers.

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Applicants respectfully contend that the Examiner has not made out a *prima facie* case of obviousness. The Examiner's misapprehends the standard of obviousness as applied in the genus/specie context. The Court of Appeals for the Federal Circuit has rejected the rejection of a undisclosed species, based on the prior art disclosure of a genus, holding that -

"[t]he fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious",

In re Baird, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994). Rather, the CAFC has required that an obviousness rejection be supported by some suggestion in prior art to create the claimed invention, stating -

"[A] proper analysis under §103 requires, *inter alia*, consideration of . . . whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed invention",

In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991) (emphasis added).

The Examiner has cited no prior art which would support such a suggestion in this case, i.e., that one of ordinary skill in the art should employ the polyester claimed in the instant application in a sustained release pharmaceutical composition. Applicants contend that one skilled in the art, faced with the teachings of Kinerton, would not be motivated to produce the *particular*, narrowly defined subgenus polyester having the ability to form a sustained release composition with a bioactive polypeptide as claimed in the instant application.

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The Examiner has failed to establish an element necessary to make out a *prima facie* case of obviousness, that of showing some suggestion or motivation in the prior art to combine prior art elements in order to arrive at the subject matter claimed in the instant application. Accordingly, the rejection based on 35 U.S.C. §103(a) is obviated.

Applicants submit the foregoing amendments and remarks are responsive within the meaning of 37 C.F.R. §1.116, and therefore, this Reply meets the requirement of a submission under 37 C.F.R. §1.114. Applicants respectfully request that all claims be examined.

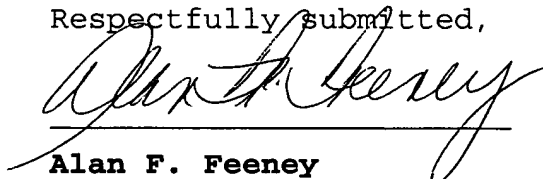
Applicants respectfully submit that the instant application is in a condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to telephone Applicant(s) attorney at (508) 478-0144 to facilitate prosecution of this application.

Please apply any charges or credits to Deposit Account No. 50-0590 referencing attorney docket number 00537-072005.

Date: 9/8/2004

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Respectfully submitted,


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